REMARKS

Claims 14, 17, 19, 23, 24, 26, 27, 29, 32 and 33 remain in the present application.

By way of review, the present invention provides a quick and effective method for assessing whether a patient has suffered axonal damage resulting from a specific group of neurologic traumas (including stroke), and the extent of that damage. Until now, there has been no effective, minimally invasive procedure for quickly determining that information which, of course, can be critical in an emergency room setting. In this method, a patient suspected of having such neurologic trauma, such as a stroke or a blow to the head sustained in a car accident, provides a sample of cerebrospinal fluid. The presence in that fluid of specific tau proteins is then determined using a monoclonal antibody raised against those proteins, and the levels of those proteins in the fluid are compared to control samples representing both damaged and undamaged states. This comparison yields information regarding whether there has been a traumatic head injury and the extent of that injury in the patient.

The Examiner has rejected claim 20, under 35 U.S.C. § 112, second paragraph, based on its use of the phrase "said...tau protein lacks the native N-terminal and C-terminal amino acids". Claim 20 has been canceled herein rendering that rejection moot.

The Examiner has also rejected all claims pending the in the present application, based on the use of the phrase "traumatic head injury" in those claims. The Examiner contends that there is not proper antecedent basis in the present application for the use of that phrase in the claims. Applicant respectfully points out that the phrase "traumatic head injury" has not been used in claim 32, and continues to assert that there is ample antecedent basis in the present application to support use of that phrase. However, in an effort to streamline what is already an overly long prosecution, Applicant has eliminated the use of the phrase "traumatic head injury" in all of the claims and has replaced it with the phrase "neurologic trauma," a phrase that has clear antecedent basis in the present application, at page 5, line 24. Further, Applicant has redefined claim 14, the broadest claim in the present application, such that the described assay is used to assess the presence of damage from acute cerebrovascular accident, primary neuronal injury, primary hemorrhage, primary vascular injury, and secondary traumatic lesions, specific phrases which are all described and exemplified, at page 4, line 17 through page 5, line 4, in the present application. In this light this, the description

of the conditions which the present assay is used to detect are now clearly defined with clear antecedent basis in the present application and, accordingly, the rejection under the first paragraph of 35 USC § 112 should be withdrawn.

Finally, the Examiner has continued his rejection of the claims, under 35 USC § 102(b), contending that they are anticipated by the disclosure of Vandermeeren et al. (WO 94/13795), which deals with the detection of Alzheimer's disease. This rejection is respectfully traversed in view of the amendments to claim 14 herein.

Claim 32 of the present application relates to the use of the assay of the present invention to detect the occurrence and the severity of an acute cerebrovascular accident in a patient. Cerebrovascular accident is a synonym for stroke (see the attached material). Vandermeeren et al. says nothing about the measurement of tau protein in the cerebrospinal fluid of a patient suspected of having a stroke. A similar situation applies to amended claim 14 (and claim 33), which clearly on its face does not encompass the use of the present assay to detect the occurrence or severity of Alzheimer's disease (a chronic condition), but rather deals with the measuring of tau protein in the cerebrospinal fluid of a patient suspected of having suffered a primary neuronal injury, a primary hemorrhage, a primary vascular injury or a secondary traumatic lesion (none of which are taught or suggested in Vandermeeren et al.—and all of which are acute conditions).

The Examiner argues that since Alzheimer's patients inherently are part of the population which have neurologic traumas of the type defined in the claims of the present application, the claimed invention is inherently anticipated by the Vandermeeren et al. disclosure. This is an incorrect reading of the law. Vandermeeren et al. describes the measurement of tau protein in cerebrospinal fluid in patients having Alzheimer's disease. There is nowhere in the Vandermeeren et al. reference that teaches or suggests the measurement of tau protein in the cerebrospinal fluid of a patient who is suspected of having suffered acute cerebral vascular accident, primary neuronal injuries, primary hemorrhages, primary vascular injuries or secondary traumatic lesions of the neurologic system. Thus, there can be no anticipation or obviousness rejection based on the Vandermeeren et al. reference. Even if there is an overlap in the populations between those having Alzheimer's disease and those having, for example, stroke, there is nothing in Vandermeeren et al. that would suggest that if an Alzheimer's patient was suspected of having suffered a stroke, a medical technician

should measure the tau protein in the cerebrospinal fluid of that patient in order to determine whether a stroke had taken place, and the severity of that stroke. To contend otherwise is the use of hindsight in its purest form and is just not supported by Vandermeeren et al. In discussing § 102 inherency rejections, Chisum indicates (at § 3.03[2][b]) that "Federal Circuit decisions emphasize that an anticipatory inherent feature or result must be consistent, necessary and inevitable, not merely possible or probable." There is no way that one can conclude that, based on that disclosure, the testing of an Alzheimer's patient, who happened to have suffered a stroke, for the purpose of measuring the tau protein in that patient's cerebrospinal fluid and thereby determining the extent of that stroke (in spite of the fact that such a connection is nowhere suggested in Vandermeeren et al.) is "consistent, necessary and inevitable," based on the Vandermeeren et al. disclosure. In that regard, the comments in *3M Unitech Corp. v. Ormco Co.*, 96 F Supp 2d 1042, 1047 (2000) are relevant: "It is not sufficient that there is a possibility that something may occur" to demonstrate an inherent anticipation; "occasional results do not show inherency." Even if the tau protein had been measured on an Alzheimer's patient who coincidentally had just recently happened to have a stroke (which would have been a purely fortuitous act), there is nothing in Vandermeeren et al. which would have suggested that those tau protein levels would be indicative of the occurrence or extent of the stroke.

The claims of the present application have now been amended to clearly distinguish them from Vandermeeren et al., which deals solely with Alzheimer's disease. As discussed above, inherency is not an appropriate grounds for rejection under these circumstances. Accordingly, it is respectfully requested that the rejection 35 USC § 102(b), based on Vandermeeren et al., be withdrawn in view of the amendments made to the claims herein.

In light of the foregoing, it is submitted that the currently pending claims in the present application are now in form for allowance. Accordingly, reconsideration and allowance of those claims are earnestly solicited. Applicant has made a good faith effort to address and be responsive to each of the grounds of the rejection made by the Examiner and thereby to place the present application in form for allowance. If any further issues remain, the Examiner is invited to call Applicant's undersigned attorney at the telephone number given below so that those issues can be expeditiously addressed and the present application placed in form for allowance.

CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

June 18, 2003

Sarah Ohlweiler

Respectfully submitted,

Frank P. Zemlan et al.

By _____

Steven J. Goldstein
Registration No. 28,079
Attorney for Applicants

FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6131

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